

NCI # NCT02224482

**Randomized Controlled Trial of an Online Multimedia Program to Boost Coping &
Function for Prostate Cancer Survivors
(PROGRESS – PRostate Cancer Online Guide & Resources for Electronic
Survivorship Service)**

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1.0 STUDY OVERVIEW

Following treatment, the vast majority of Pca survivors suffer from treatment-related symptomatology, specifically urinary and sexual dysfunction, in addition to facing psychosocial and practical challenges. There is a need for comprehensive programs with demonstrated efficacy to help patients cope with these challenges. We propose to develop and evaluate a comprehensive and innovative multimedia program designed to facilitate the post-treatment transition into survivorship. The design of the proposed intervention, the Virtual Survivorship Resource Center for Prostate Cancer (VSRC-PC), will be theoretically based on the team's Cognitive-Social Health Information Processing Model. The VSRC-PC will focus on promoting adaptive coping within four key post-treatment domains: 1) Physical Dysfunction (e.g., physical symptoms); 2) Emotional Well-Being (e.g., fear of recurrence); 3) Interpersonal Concerns (e.g., sexual intimacy issues); and 4) Practical Barriers (e.g., medical follow-up challenges). Content for these domains will be organized in a virtual resource center and will consist of: 1) provision of related information through text, graphics, voiceovers, and animation; 2) videos of health care experts answering frequently asked questions; 3) videos of prostate cancer survivors describing their experiences and modeling competencies and coping strategies; and 4) skills training to improve communication between Pca survivors and family and healthcare providers. Program content will be developed through literature and evidence-based content review, expert input, and input from multi-ethnic survivor focus groups. To ensure adequate and appropriate program content and optimal functionality, an iterative process of review, revision, and user and usability testing will be employed. Intervention efficacy will be evaluated through a two-arm, prospective randomized controlled trial. A total of 600 patients (200 from Fox Chase Cancer Center) will complete the study. Data will be collected at baseline, and at 1-, 3- and 6- month follow-up. The primary outcome variable will be adaptive coping, and the secondary outcome will be maladaptive coping. A theory-based test of mediators of intervention effects (e.g., self-efficacy), and moderators (e.g., monitoring style) will also be performed. The proposed research will be the first RCT to evaluate not only a comprehensive but also highly disseminable and self-sustaining intervention for facilitating post-treatment adaptation among early-stage Pca survivors.

2.0 INTRODUCTION/RATIONALE

2.1. Prevalence of Early Stage Pca Patients, their Adaptational Challenges, and the Availability of Interventions to Address their Survivorship Needs

Prostate cancer (Pca) is the most common solid tumor malignancy among US men and the second leading cause of cancer mortality, accounting for an estimated 192,280 new diagnoses and 27,360 deaths in 2009 [1]. Pca survivors comprise 42% of the five million male cancer survivors in the U.S., and has been steadily growing over the past 10 years [2]. An estimated 91% of new prostate cancer cases are diagnosed at an early stage (stages I and II, in which the tumor is confined to the prostate [3]), for which the 5-year relative survival rate approaches 100% [1]. Most localized prostate cancer patients elect to undergo active treatment rather than watchful waiting or active surveillance; the most commonly selected treatments are radical prostatectomy (RP) and radiotherapy (RT) [4]. Each of these treatment modalities is likely to result in substantial rates of treatment-related physical complications and associated psychosocial morbidity [5, 6]. These complications and related adverse psychosocial challenges can be difficult for patients to optimally manage, especially in the absence of comprehensive informational and skills training programs. Indeed, Pca survivors report that their informational and psychosocial needs are largely neither assessed nor addressed during the transition from active treatment to survivorship [7-10]. Indeed, most available interventions for RP and RT

survivors consist of either physical or pharmaceutical aids (e.g., for erectile dysfunction) alone or consist of some combination of educational, informational, and psychosocial content to address stress management and practical matters [11-13]. These interventions, although partially effective in reducing distress, are often fragmented, labor and resource intensive, and have not been consistently adopted in clinical practice beyond the funding period. Given the great dissemination potentials of use of the Internet, the current study therefore proposes to develop and evaluate an innovative, theory-driven web-based multimedia program (a Virtual Survivorship Resource Center for Prostate Cancer: VSRC-PC) that comprehensively addresses Pca survivor-relevant domains of interest with a view to empowering Pca survivors to not only effectively manage treatment-related side effects and adverse psychosocial sequelae, but also to cope effectively with the interpersonal and practical difficulties that they often experience. Enhanced coping (our primary outcome), in turn, should allow patients to achieve and sustain better health-related quality of life (HRQoL) during the post-treatment early survivorship period, in the survivorship life domains outlined below (our secondary outcomes).

Themes in the challenges accompanying the transition to early survivorship are remarkably similar across clinical, qualitative, and empirical reports, and lead us to conclude that Pca patients completing primary treatment are likely to benefit from educational and skills training information in four life domains: physical function, emotional well-being, interpersonal concerns, and practical barriers. These four domains have been well established in the cancer survivorship literature [14] and were used to guide the content of NCI's *Facing Forwarding* brochure, the first NCI publication addressing survivorship issues.

2.2. Physical Function During Early Pca Survivorship

Primary, curative treatment includes radical prostatectomy (RP) and radiotherapy (RT), including both external beam radiation therapy (EBRT) and brachytherapy (BT) [4]. Both RP and RT significantly reduce disease-specific mortality, overall mortality, and the risks of local and distant progression of localized prostate cancer [15]. However, each type of treatment is associated with **urinary, sexual, and bowel dysfunctions** [16] causing distress or “bother” that has the potential to significantly undermine a patient’s HRQoL. Urinary symptoms include incontinence and bladder irritation resulting in urgency, pain, and frequency. For RP patients, a large percentage (~50%) experience moderate levels of urinary incontinence at 2 months post-surgery [17]. Sexual symptoms include depressed libido, erectile dysfunction, and difficulty in achieving orgasm. More than 90% of RP patients experience moderate to severe sexual deficits, which peak at 3 months post-surgery and then improve only minimally through 24 months [17]. Bowel symptoms include urgency, frequency, fecal incontinence, bloody stools, and rectal pain. For EBRT and BT patients, a moderate (~34) to larger percentage (~45) experience mild urinary symptoms at 2-month post-treatment, which slightly improve from 6 through 24 months [18]. Therefore, establishing reasonable expectancies and providing information about the prevalence and management of these effects of treatment regarding the nature of recovery is critical for Pca patient transition from active treatment into survivorship. If these physical effects come as a surprise, they may trigger self-imposed demands to push one’s misattributions about the meaning of symptoms. Persistent prevalence of physical dysfunctioning and information about how to manage this issue are reported by Pca patients [9, 19, 20]

2.3. Emotional Well-Being During Early Pca Survivorship

The psychosocial impact of cancer is significant, including **reduced quality of life, depression and other psychiatric disorders, distress, and adjustment difficulties** [21-23]. In a large

cohort of localized prostate cancer patients (the overwhelming majority of whom underwent RP and RT), Bacon et al (2002) found that patients were substantially more distressed due to sexual, urinary, and bowel symptoms, in comparison with pretreatment baseline levels. In another study in which all but 8% of participants underwent either RP or RT, there were marked differences between Pca patients and comparable cancer-free controls with respect to lower **sexual intimacy, sexual confidence, and sense of masculinity** [24]. In sum, Pca patients experience **poor self-concept, embarrassment, and shame associated with urinary and bowel problems**, often leading to an isolated lifestyle in an effort to limit social activities outside of the home and curtail interactions with friends and family [25-27]. The **fear of rising prostate-specific antigen levels and recurrence of cancer** can also negatively affect psychosocial adaptation and HRQoL outcomes of Pca patients [28]. In addition, studies reported that long-term survivors expressed **concerns about getting another type of cancer** at levels similar to concerns about recurrence, ranging from 26 to 36%, with prostate cancer survivors most likely to have this concern [29].

2.4. Interpersonal Concerns During Early Pca Survivorship

Pca patients tend to become increasingly dissatisfied with their **communication with physicians** as they continue to live with the aftereffects of treatment, highlighting the gap in patient-provider communication during the early survivorship phase [30]. Further, patients often had difficulties interacting with the medical team, including the need to navigate between the primary provider and the oncology specialist (e.g., when and where to call if encountering a troubling symptom) [31, 32]. In addition to communication with the medical team, the after-effects of prostate cancer treatment can cause problems with **interpersonal relationships** that may significantly disrupt the lives of men and their spouses/partners. Adjustment to treatment-related adverse effects places demands on couples' resources and requires effective yet intimate communication. However, existing support services for men with prostate cancer are most often oriented towards the medical and related needs of the patient. Therefore, greater attention is needed to the couple relationship, as well as to the social context in which patients find themselves [22, 33, 34]. For example, family, friends, and co-workers can promote unreasonable expectancies that the patient will return promptly to their old roles prior treatment once treatment is completed, and cancer patients often comment on the relatively sharp downturn in active social support at this time [35].

2.5. Practical Barriers During Early Pca Survivorship

There are a number of practical issues that confront Pca patients, including the difficulties of applying for **financial assistance** to cover medical costs, obtaining **insurance** for future medical care, **securing legal services** in cases of discriminatory workplace or **accessing care practices** [36, 37]. Pca patients also often need assistance in delineating and using a **medical care follow-up or survivorship plan**. It is important to educate patients about the importance of having a primary cancer treatment document and a survivorship cancer plan. In addition, Pca patients specifically often need assistance with regard to the purchase and use of aids, supplies, and materials relating to the **management of their treatment-related side effects**, e.g., for urinary, sexual, and bowel dysfunction [36].

2.6. The Role of the Internet in Providing Health-Related Information

The Internet is rapidly becoming one of the most utilized dissemination channels for health-related information. In the U.S., approximately 80% of adults report using the Internet to address their health information needs [38]. In particular, web-based interventions are feasible for

individuals seeking cancer information, of interest to individuals with cancer, and effective in promoting health behavior change relative to individualized print materials. Although individuals have become familiar with and accustomed to accessing medical information on the Internet, little of the information available is empirically based or theoretically guided. An exception is Gustafson's Comprehensive Health Enhancement Support System (CHESS), a web-based information and support program that has been developed for cancer patients and other groups. Research has demonstrated that CHESS is user-friendly and well accepted by individuals of diverse demographic background [39-41]. Data with breast cancer patients and a randomized, controlled trial with HIV+ patients suggest positive effects on mood, quality of life, and health outcomes [42, 43]. Dr. Gustafson will provide his expertise for the proposed trial as a consultant. Our theory-guided breast cancer survivorship multimedia program demonstrates the feasibility of using the Internet as a delivery channel with 65% of participants spending 15-25 minutes in the program per access.

In sum, it is important for researchers to rapidly design, produce, and evaluate interactive web-based multimedia software products, particularly geared to offset the shortage in health care personnel and to capitalize on recent developments in health psychology messaging and health communications research. In the case of web-based multimedia interventions for cancer patients, most studies have focused on breast cancer [44]. Those studies that have focused on Pca patients have mainly focused on the diagnostic and treatment phases, but have not addressed prostate cancer survivorship.

2.7. Use of a Theoretical Model to Inform and Guide Intervention Development

One of the signature characteristics of the proposed research is that the VSRC-PC intervention will be informed and guided by an integrative theoretical framework (developed by the research team), the *Cognitive-Social Health Information Processing Model* (C-SHIP) [45, 46]. The C-SHIP model identifies five key constructs, all of which are common denominators in most contemporary views about how individuals adapt to health challenges: 1) cancer-relevant interpretations; 2) beliefs and expectations about cancer treatment and disease outcomes, as well as beliefs about one's own self-efficacy in dealing with health-related challenges; 3) cancer-relevant goals and values; 4) cancer-relevant affective and emotional states; and 5) self-regulatory competencies and skills for generating and maintaining goal-oriented health-related behaviors. Consistent with our existing psychosocial programs, we will operationalize these theoretical constructs within the proposed intervention by: 1) providing accurate information; 2) creating realistic expectations and promoting self-efficacy; 3) exploring the patient's goals and values and encouraging behavior consistent with them; 4) validating feelings and facilitating emotional support, and 5) providing information and training to maximize self-regulatory competencies and skills. The expected net effect of these operational components is increased use of *adaptive coping* (active coping, planning, positive reframing, acceptance, using emotional and instrumental support), the primary outcome variable of the trial, *since the target result of each component is enhanced ability and predisposition to act adaptively*. Our intervention objectives derive directly from the C-SHIP theoretical constructs and the intervention operationalizes achievement of the objectives. Our hypothesized moderator, *monitoring style*, is conceptualized within C-SHIP as a stable tendency for individuals to select, encode, interpret, react to affectively, and manage threatening medical health information in either of two signature ways (i.e., using a *high monitoring style*, characterized by scanning for and magnifying stress-related cues relevant to one's health, or using a *low monitoring style*, characterized by distracting from and minimizing such cues). Research has documented that these styles predict individual differences in coping and cognitive-affective responses to health-related stressors [47-49]. Because high monitors are particularly at increased risk for the adverse consequences

of health threats [48], the proposed intervention is likely to have larger salutary effects among high monitors than low monitors because of their greater need for alleviation of such adverse effects and the potential of such effects to interfere with effective coping.

2.8. Use of an experienced interdisciplinary team

We have assembled an interdisciplinary team with expertise in individual differences in stress processing and adjustment among cancer survivors, theory-guided interventions and multimedia programs; consumer health informatics applications; cancer and communication interventions and disparities; psychosocial issues, quality of life, adjustment to prostate cancer, and multimedia development; survivorship and mixed methods research; and prostate cancer biology, treatment, and physical effects of treatment (clinical investigators). We will collaborate with [REDACTED], who developed our prostate cancer treatment and breast cancer survivorship multimedia programs during an earlier research collaboration. The research team has more than a decade-long history of collaborating and publishing together [45-48, 50-58].

3.0 STUDY OBJECTIVES

Aim 1: Develop a Virtual Survivorship Resource Center for Prostate Cancer (VSRC-PC) Designed to Facilitate Post-treatment Adaptation of Early-Stage Pca Patients. The design of the proposed intervention is theoretically based on the team's Cognitive-Social Health Information Processing Model (C-SHIP [45, 46]) and informed by our existing multimedia prostate cancer support system for treatment decision making at diagnosis. The VSRC will focus on promoting adaptive coping within four key post-treatment domains, as identified by the extant literature and our theoretical model: 1) Physical Function (e.g., physical symptoms); 2) Emotional Well-Being (e.g., fear of recurrence); 3) Interpersonal Concerns (e.g., sexual intimacy issues); and 4) Practical Barriers (e.g., medical follow-up challenges) [14]. Content for these domains will be organized in a virtual resource center and will consist of: 1) provision of related information through text, graphics, voice-overs, and animation; 2) videos of health care experts answering frequently asked questions; 3) videos of prostate cancer survivors and their families describing their experiences and modeling competencies and related coping strategies; and 4) skills training to improve communication between Pca survivors and family and healthcare providers. We will take full advantage of the highly interactive nature of the multimedia environment to encourage self-navigation and self-tailoring. Program content will be developed through literature and evidence-based content review, expert input, and input from diverse, multi-ethnic survivor focus groups. Timely software development will be implemented by a close collaborator [REDACTED]. To ensure adequate and appropriate program content and optimal functionality, an iterative process of review, revision, and user and usability testing will be employed.

Aim 2: Evaluate the Efficacy of the VSRC-PC in a Randomized Controlled Trial. Early-stage Pca patients who are undergoing radical prostatectomy and radiotherapy will be recruited at treatment completion from four sites within three institutions with diverse patient populations and well-established collaborative linkages. Data will be collected at baseline and 1-, 3- and 6-months post-baseline. The control group (Group 1; n = 300) will receive NCI's *Facing Forward* and *What You Need to Know about Prostate Cancer*. The intervention group (Group 2; n = 300) will receive the same NCI print materials as Group 1, plus the VSRC-PC. The primary outcome variable will be adaptive coping, which includes active coping, planning, positive reframing, acceptance, and the use of emotional and instrumental support. Secondary outcomes will consist of maladaptive coping (denial, behavioral disengagement, self-blame) and adaptation in the four post-treatment domains. **Hypothesis 1:** Group 2 participants will show significantly

higher levels of adaptive coping, significantly lower levels of maladaptive coping, and greater adaptation than Group 1 participants in the short-term and at 3- and 6-month follow-up assessments.

Aim 3: Conduct Mediator and Moderator Analyses of Intervention Efficacy. Based on the C-SHIP framework, we will explore both mediators (self-efficacy) and moderators (monitoring) of intervention impact. **Hypothesis 2:** Adaptive coping will be *mediated* by enhanced self-efficacy for managing treatment-related side-effects psychosocial challenges for Group 2 but not for Group 1. **Hypothesis 3:** Monitoring style will *moderate* the impact of the intervention: high monitors (who scan for and amplify threat-relevant cues) will benefit more from the intervention than low monitors (who distract from health threats). **Innovation and Significance:** The proposed research is innovative because: a) it will be the first RCT to evaluate a comprehensive intervention for facilitating post-treatment adaptation among early-stage prostate cancer patients; b) the design and development of the intervention will be guided and informed by an innovative application of a state-of-the-science theoretical framework; and c) the intervention can be self-sustaining. If found effective, the program will address critical unmet needs of prostate cancer survivors during the initial post-treatment period, in a proactive and readily disseminable fashion.

4.0 SELECTION OF PARTICIPANTS

4.1 Individual Interviews

In order to determine when to best implement the intervention, a total of approximately 5-10 men, who are actively being treated for prostate cancer, or who have already decided on their treatment, will be interviewed to assess the psychosocial concerns they experience during treatment. These intercept questions will be combined with the focus group questions to guide the individual interview and obtain additional data. Interviews will be audio-recorded.

Participants are eligible if they:

- 1) have received a diagnosis of localized disease confined to the prostate, with no regional lymph node or distant metastasis (stages T1, T1a, T1b, T2, T2a, T2b; [3]);
- 2) are currently being treated or have decided on their treatment process (radical prostatectomy or radiation therapy);
- 3) are 18 years of age or older;
- 4) are able to communicate in English;
- 5) are able to give consent.

4.2. Focus Group (Phase 1) Eligibility Criteria

Three focus groups (two from FCCC and one from MSMC) will be conducted with data from each group being used to inform and refine the subsequent groups. The three focus groups will reflect different treatment modalities: Group 1 – Radical Prostatectomy; Group 2 – Radiation Therapy; Group 3 – Either therapy. Focus groups will consist of racially and ethnically diverse prostate cancer survivors (N=15), with some individual interviews occurring if needed.

Participants are eligible if they:

- 1) received a diagnosis of localized disease confined to the prostate, with no regional lymph node or distant metastasis (stages T1, T1a, T1b, T2, T2a, T2b; [3])
- 2) completed either radical prostatectomy (Group 1 or Group 3) or radiation therapy (external beam radiation therapy or brachytherapy; Group 2 or Group 3) within the past 12 months;
- 3) are 18 years of age or older;

- 4) are able to communicate in English;
- 5) are able to give consent; and,
- 6) are within traveling distance to FCCC and MSMC.

4.3 User/Usability Testing (Phase 2) Eligibility Criteria

A total of 20 prostate cancer survivors (5 from each site) will provide feedback on the VSRC-PC components.

Participants are eligible if they:

- 1) received a diagnosis of localized disease confined to the prostate, with no regional lymph node or distant metastasis (stages T1, T1a, T1b, T2, T2a, T2b; [3])
- 2) completed either radical prostatectomy or radiation therapy (external beam radiation therapy or brachytherapy) within the past 12 months;
- 3) are between 55 and 85 years of age
- 4) are able to communicate in English;
- 5) are able to give consent; and,
- 6) are within traveling distance to FCCC, MSMC, Rutgers Cancer Institute of New Jersey, or TUH.

4.4. RCT (Phase 3) Eligibility Criteria

The target sample (N=600) will be men who have recently been treated for prostate cancer. A multi-ethnic survivor group will be recruited from all three participating sites. According to the tumor registry data, on average a total of 1000 eligible prostate cancer patients are seen per year at the three recruitment sites. Of these, about 50% (n=500) are expected to have Internet access [63]. Based on our prior experience with the prostate population [47], we assume that 48% of eligible patients will agree to enroll in the study, yielding a total of approximately 240 participants per year at the four recruitment sites. We therefore conservatively estimate that we can accrue 20 participants per month over a 30-month period across the four sites to reach our goal of 600 participants. In addition, if unanticipated problems with accrual occur, we will have ready access to recruit survivors through partner hospitals. This added source of accrual will provide us with a significant cushion, which has not been figured into our accrual calculations. We also project that we will retain approximately 80% of the participants whom we recruit, allowing us to conservatively estimate that 480 participants will complete the study. Power analysis indicates that with 480 participants, the study will be powered to detect a modest effect size (0.1) with at least 84% statistical power (see Section 7.4). With regard to minority recruitment, we project that approximately 20% of the recruited participants will be African American (n=120) men.

Participants are eligible if they:

- 1) received a diagnosis of localized disease confined to the prostate, with no regional lymph node or distant metastasis (stages T1, T1a, T1b, T2, T2a, T2b, T2c, T3, T3a, T3b, T3c [3]);
- 2) within one year completion of either radical prostatectomy or radiation therapy (external beam radiation therapy or brachytherapy);
- 3) have access to an IBM-compatible or Macintosh personal computer with Internet access (either in home or at a community center);
- 4) are 18 years of age or older;
- 5) are able to communicate in English; and,
- 6) are able to give consent.

5.0 REGISTRATION PROCEDURES

5.1. Setting

[REDACTED] The research team has a decade long history of collaboration and currently collaborates on a program project. The proposed project will benefit from many of the communication routines that have been established through these past and ongoing collaborations [REDACTED]

[REDACTED]

5.2. Individual Interviews Recruitment Procedures

Approximately 5-10 prostate cancer patients who are currently receiving treatment [REDACTED]

[REDACTED] A member of the research staff will first meet with the prostate team to describe the research study and explain the eligibility criteria. The research assistant will be available during clinic hours to meet with potential participants identified through these sources, and the interview may be conducted in-person or via phone at a later date. This interview will be audio-recorded. Participants will sign a consent form at the time of the interview.

5.3. Phase 1: Focus Group Recruitment Procedures

Three focus groups with a total of approximately 30 racially and ethnically diverse, prostate cancer survivors will be conducted [REDACTED]

[REDACTED] A member of the research staff will first meet with the prostate team to describe the research study and explain the eligibility criteria [REDACTED]

[REDACTED] The research assistant will be available during clinic hours to briefly meet with potential participants who have been identified through these sources, and solicit participation. Flyers will also be distributed to patients with the research staff's contact information. Patients who are interested, but who do not have the time to meet with the staff member, will provide their contact information and will then be contacted via phone by a study staff member who will describe the study in more detail and schedule a date for the interested patient to attend a focus group or individual interview. For patients who are available on site, the staff member will then describe the study and schedule a date for the focus group or individual interview. Participants will sign the consent form at the time of attending the focus group or interview. Participants will receive a \$20 gift card as compensation.

[REDACTED] Potential participants will be contacted by [REDACTED] research assistant

by phone or in person for their verbal consent for tracking their eligibility. Once eligibility is confirmed, the research assistant will describe the study in more details, solicit patients' participation, and schedule a date for a focus group or an interview. Prior to the start of the focus groups or patients' interviews, signed consents will be obtained from patients. Participants will receive a \$20 gift card for their time.

5.4. Phase 2: User/Usability Testing Recruitment Procedures

[REDACTED]

[REDACTED] A member of the research staff will first meet with the medical team to describe the research study and explain the eligibility criteria. [REDACTED]

[REDACTED]

[REDACTED] The research assistant will be available during clinic hours to briefly meet with potential participants who have been identified through these sources, and assess interest. Flyers will also be distributed to patients with the study staff's contact information. Patients who are interested, but who do not have the time to meet with the staff member, will provide their contact information and will then be contacted via phone by a study staff member who will describe the study in more detail, and schedule a date for the interested patient to attend the individual interview. For patients who are available, the staff member will then describe study and schedule a date for the individual user testing interview. Participants who are interested will sign a consent form before they complete the testing. Participants will receive a \$20 gift card for their time.

[REDACTED]

[REDACTED]

[REDACTED]

5.5. Phase 3: RCT Recruitment Procedures

potential participants will be identified in several ways through the Prostate Cancer Patient Care Team, as described above. To reach additional patients, will post contact information in the E-news daily newsletter which is circulated daily to the staff

Potential participants will be sent a letter describing the study and asked to contact staff if they are not interested or they will receive a call within two weeks. Patients who are interested and found to be eligible will be contacted via phone using the attached phone script. The study staff member will then mail the potential participant the Informed Consent Document and follow the remaining recruitment procedures described below.

A member of the research staff will first meet with the prostate team to describe the research study and explain the eligibility criteria.

Flyers will also be distributed to patients with the study staffs contact information. Patients who are interested, but who do not have the time to meet with the staff member, will provide their contact information and will then be contacted via phone by a study staff member. The staff member will describe the study in more detail and assess interest. Those patients who contact study staff via phone will be informed of further details about the study using the attached phone script. Those patients who are eligible but decline the study will be asked for the reason of their decline. Reasons for decline will be recorded and the data will be analyzed at the end of the study and reported in publications. The study staff member will then obtain written informed consent (if in person) or mail the potential participant the Informed Consent Document . After providing consent, eligible men who wish will be given the baseline assessment to complete at home with a self-addressed stamped envelope to return once completed. Eligible men who wish to complete the survey with assistance will be scheduled for a baseline assessment via phone or in person at the current or next follow up appointment. If interested in completing the baseline online, eligible men will be given a survey link to access the survey in the REDCap data system. If enrolled in the intervention group, at enrollment patients will receive a postcard listing their unique username and password to access the multimedia website during participation in the study. Participants will receive a \$20 gift card for each (of four) assessments completed.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

6.0 RESEARCH DESIGN/METHODS:

6.1. Study Overview

The study will develop and test a prostate cancer survivorship program, uniquely designed to comprehensively assess and address patient domains of concerns, and that is also readily disseminable through use of a multimedia format as an adjunct to care. The developmental process will entail a series of focus groups, user and usability testing, and refinement and final production. Based on social-cognitive theory and health communications best practice approaches, as well as our previous experience with print, telephone, and multimedia approaches, the development process will use a rigorous vetting and user testing to ensure that the materials and messages are relevant, evidence-based, and easily understandable. The actual program elements, as well as the usability of the program prototype, will be user-tested prior to the RCT. Once the program is developed, it will be tested during a six-month RCT with 600 ethnically and racially diverse prostate cancer survivors.

6.2. Phase 1: Survivor Content Theme Identification Focus Groups Overview

Following an update of our systematic review of the literature to integrate extant findings into a comprehensive description of survivor needs, nine multi-ethnic focus groups with survivors (10 in each focus group) will be recruited, with individual interview occurring if needed. Each will provide input based on their retrospective experiences as patients, with particular reference to the early survivorship phase after treatment completion. The audiotaped record of focus group proceedings will be transcribed and the transcript analyzed to identify relevant content concerning the post-treatment phase. This information will be used to assist in the development of VSRC-PC content.

6.2.1. Focus Group Assessments

Participants will be asked open-ended questions about their post-treatment experience. Topics will include physical symptoms, emotional symptoms, interpersonal concerns, and communication difficulties. Additionally, participants will be asked open-ended questions concerning the importance of the proposed components of the VSRC-PC.

6.3. Phase 2: Evaluation of the Prototype through User/Usability Testing

To facilitate the development and refinement of the program prototype, user testing will be conducted to elicit input from the target audience. We will conduct pretesting of the content, visuals, and approaches of the VSRC-PC with a wide variety of populations, including diverse ethnic groups and patients within the different age brackets in which prostate cancer is diagnosed. We will recruit 15 individuals to gather adequate representation to inform production decisions. In addition, each contract team will conduct limited pretesting with survivors at their affiliated cancer centers. We will also conduct alpha and beta usability testing of the VSRC-PC to test the functioning of the software, using observation techniques recommended by NCI's own usability laboratory (www.usability.gov). Participants will be asked to use the "Think Aloud" technique to provide insight into how individuals use and interact with the program. Weaknesses in the user interface can be readily detected using this technique, along with information gaps and software errors. It is generally assumed that a small number of individuals (< 6 individuals) are sufficient to detect more than 80% of potential software errors, glitches, and gaps in a program. The different pretesting and usability testing phases will recycle throughout the 18 months of the development timeline. We will track the recommendations and usability testing results and will work closely with [REDACTED] to produce the final version of the VSRC-PC.

6.3.1. User/Usability Testing Assessments

After interacting with a particular VSRC-PC component, participants will be asked open-ended and close-ended questions regarding quality and ease of use. As participants navigate the VSRC-PC, measures will include time to complete, expressions of frustration, time spent "wandering" with mouse, navigation errors, and 'back' button clicks. Participants will also be asked questions about individual VSRC-PC components.

6.4. Phase 3: RCT Overview

Telephone or in person assessment will be used to perform baseline screening at the completion of treatment for eligibility/exclusion, as well as baseline assessment of all outcome, potential moderator, and mediator variables, and follow-up assessments. If recruited by phone, the consent form will be mailed, along with an addressed, stamped envelope. When the consent form is received, the participant will be contacted and baseline assessments will be completed. Upon completion of the baseline assessment, the participant will be randomly assigned to the intervention or control group and mailed the appropriate materials. The participant will be contacted by phone three additional times (at 1-, 3- and 6- months post baseline assessment). Phone interviewers will be unaware of condition assignment. Participants may complete the follow up assessments via phone, mail or online via the REDCap data system. Table 1 displays the variables, measures, and time points of administration. See Appendix C for measures and their questions. Each assessment will take approximately 45 minutes to complete.

6.5.1 Randomization Protocol and Assessment

Programmed into the baseline assessment will be stratification and randomization algorithms that will equalize the stratified groups across experimental conditions ($n = 300/\text{group}$). The Biostatistics and Bioinformatics Facility at FCCC will be responsible for programming all of the telephone assessments, including the stratification and randomization algorithms for the baseline telephone assessment. Within one week after the baseline assessment, participants will receive mailed materials pertaining to their assigned interventions. Control participants will receive the two NCI brochures described below. Intervention participants will receive the brochures as well as a package with detailed information concerning the objectives of the VSRC-PC and its content coverage and functionality, as well as information about how to access the website, including the unique passcode assigned.

6.5.2 Description of the Control Group Intervention

The control group will receive *Facing Forward: Life after Cancer Treatment*, the NCI's manual for cancer survivors. This 61-page, recently-revised manual (NCI, 2006) includes major sections on Getting Follow-up Medical Care, Ways to Manage Physical Changes, Body Changes and Intimacy, Your Feelings, Social and Work Relationships, and Reflection. These topics intersect well with the four survivorship domains we have identified which makes this an ideal comparison intervention to control for attention and preparation for the survivorship transition. While the appropriate life domains are presented, and thus of relevance to survivors, *Facing Forward* does not contain detailed information specifically for men with prostate cancer. Hence, in order to ensure that control participants receive prostate cancer-specific information and thereby increase comparability with the intervention condition, they will also receive *What You Need to Know about Prostate Cancer* (NCI, 2003), a pamphlet that provides useful information regarding prostate cancer diagnosis and treatment. However, neither of the print materials contains such features as specific recommendations for using active coping strategies and promoting self-efficacy, skills provision and training exercises, nor the interactive capability, self-tailoring, and multi channel presentation (e.g., video) offered in the VSRC-PC.

6.5.3. Description of the VSRC-PC

The VSRC-PC will facilitate early post-treatment survivorship by providing a comprehensive resource to meet the information, competency and skills building, and psychosocial needs of target users in a proactive fashion. It is theoretically-guided to assess and address the four identified domain challenges of prostate cancer survivors (physical function, emotional well-being, interpersonal concerns, practical barriers), based on health communication best practices and social-cognitive theory. An outline of the VSRC-PC is presented in Table 1. The VSRC is designed along three dimensions: content, modules for content delivery, and contextual setting. The *content* consists of the information, competencies, skills, and coping strategies required for optimal adjustment. The *modules for content delivery* include text, graphics, voice-overs, and animation; videoclips of doctors and other content experts addressing selected topics through explanation, instruction, and answers to user-selected questions from dropdown menus; prostate cancer survivors describing their experiences and modeling domain competencies, skills, and coping strategies; and a communication module providing training in communicating with spouse, physicians, family, and friends. The *contextual setting* involves the use of a metaphor of a virtual health center, consisting of a reception area, library, physician offices, and a group meeting room; and the presence of a Virtual Cancer Navigator (VCN), who greets the user in the reception area, provides an introduction to the early survivorship phase, and serves as a guide to navigating and using the program. Intervention program features include a tutorial program to facilitate program use and navigation; use of dropdown menus to provide for interactivity; a needs assessment component to support self-tailoring of program use through guidance to personally relevant program areas; provision for identification of common misinformation and misconceptions about prostate cancer and post-treatment symptoms and

recovery; a program component that elicits patient survivorship values and goals and supports patient behaviors consistent with them; inclusion of normalizing messages and encouragement throughout the program to foster psychological adjustment; and inclusion of a help desk for provision of technical assistance in use of the program.

6.5.4. RCT Assessments

Following informed consent, a Research Assistant will conduct the initial baseline assessment in person or by phone. Following baseline assessment, participants will be mailed materials pertaining to their assigned condition. Participants will be informed that they will be contacted at 1-, 3-, and 6-months post-baseline. All assessments will take approximately 45 minutes. These follow-up assessments will take place by phone.

6.5.5. RCT Study Retention and Program Engagement Strategies

We will use various approaches to maximize initial and follow-up rates of intervention use and thereby enhance study completion: 1) monetary incentives (\$20) to reimburse for time and effort for each assessment; 2) maintaining current contact information, including home phone and cell numbers and email addresses for follow-up purposes; 3) monthly postcards to participants in both groups to encourage the use of intervention materials; and 4) for VSRC intervention participants who provide their email addresses, monthly tickler emails will be sent to both groups in order to promote intervention use. We will also employ evidence-based recommendations [64] for encouraging web-based engagement using marketing messages. For example, we will rotate the program modules or topics to be highlighted in each monthly tickler to sustain and attract participants' continuous use.

6.5.6. RCT Measures

All measures are listed in Table 1. Except where noted, all measures were given at baseline and each follow-up assessment.

Table 1. Measures and times of assessment (*denotes primary outcome measure)					
VARIABLE	MEASURE	TIME OF ASSESSMENT			
		Baseline	1 mo	3 mo	6 mo
OUTCOMES					
<u>Coping</u> Use of Adaptive Coping*	Cancer Coping Questionnaire	X	X	X	X
<u>Physical Functioning</u> Disease-specific quality of life	EPIC-26-SF (subscales: urinary, bowel, sexual dysfunctions)	X	X	X	X
<u>Emotional and Social Well-being</u> Bother from physical dysfunctions	EPIC-26-SF	X	X	X	X

<u>Interpersonal Concerns</u> Medical team	CARES-SF Medical Interaction Subscale (subscales: difficulty communicating with medical team, problems obtaining information from medical team)	X	X	X	X
Marital problems	CARES-SF (marital problems subscale)	X	X	X	X
<u>Practical Barriers</u> Practical concerns	Author-Constructed Practical Concerns Scale and Selected items from FOCUS	X	X	X	X
MODERATORS					
Background variables	Age, education, race/ethnicity, Prostate Cancer diagnosis and initial treatment information, Charlson Co-Morbidity Index**	X	X	X	X
Monitoring Style	MBSS CES-D-SF	X			
Negative affect/general distress	POMS Short Form – Depression and vigor-activity subscales /Anxiety Subscales /Anger/Frustration items	X	X	X	X
Health Literacy	Chew 3-item scale	X			
MEDIATORS					
Self-Efficacy for the survivorship phase	Self-Efficacy for Re-Entry Scale	X	X	X	X
Patient Activation	Measure of Current Status Patient Activation Measure	X	X	X	X
PROCESS EVALUATION					
Intervention Component Use and Satisfaction	Author-constructed scales		X	X	X

Background/Moderator Variables

- 1) Demographics.** Age, education, race/ethnicity and prostate cancer diagnosis and initial treatment information will be assessed at baseline only.
- 2) Comorbid conditions.** At baseline only, this will be assessed with the *Charlson Comorbidity Index* [65], a weighted index that takes into account the number and seriousness of comorbid diseases (e.g., liver disease, diabetes).
- 3) Monitoring style.** This will be assessed with the Monitoring-Blunting Style Scale (MBSS), which measures high monitoring style versus low monitoring style [49].

- 4) **Affect.** Negative affect/distress will be assessed with the depression-dejection, tension-anxiety and vigor-activity subscales of the short form of the Profile of Mood States (POMS) [66] and also using the Center for Epidemiological Studies Depression Symptoms short-form scale (CES-D-SF) [67].
- 5) **Health Literacy.** This will be assessed with three questions from Brief Questions to Identify Patients with Inadequate Health Literacy [68].

Outcome Variables

- 1) **Use of Coping.** The Cancer Coping Questionnaire will be used to measure active and adaptive coping. The subscales include Individual scale items: Coping (items 2, 6, 7, 11, 12), Positive Focus (items 1, 9, 14), Diversion (items 3, 4, 8), and Planning (items 5, 10, 13), and interpersonal scale items (15-21) [69]
- 2) **Physical Functioning.** This will be measured using the *Expanded Prostate Cancer Index Composite – Short Form (EPIC 26-SF)*, a 26 item shortened version of EPIC, a 61 item questionnaire for assessing urinary, bowel, sexual, and hormonal dysfunction and distress/bother in prostate cancer patients [70]. Only the urinary, bowel, and sexual subscales will be included because hormonal dysfunctions have not been documented for RP and RT patients. Both dysfunction subscale scores and an equally weighted additive composite of such scores will be employed to assess Disease-Specific Quality of Life. The distress/bother items will be included in the scale because of their use in the Emotional Well-Being domain, but will be excluded from the physical functioning score.].
- 3) **Interpersonal Concerns.** *Satisfaction with communication in medical interactions* will be assessed with two subscales from the *Cancer Rehabilitation Evaluation System* (CARES; [71]): difficulty communicating with the medical team, and problems obtaining information from the medical team. The *marital problems subscale* of CARES will assess *marital problems*.
- 4) **Practical barriers.** This will be assessed with an author-constructed Practical Concerns Scale supplemented with relevant items from the Follow-up Care Use Among Survivors (FOCUS) study [72].

Mediator Variables

- 1) **Self-efficacy for the survivorship phase.** This will be assessed with the *Self-Efficacy for Re-Entry Scale*, an adapted version of a measure developed and used in one our previous and ongoing work (CISRC project 3), since this construct has been shown to play a key role in intervention impact.
- 2) **Confidence in ability to manage symptoms related to prostate cancer.** This will be assessed with the 13 items from the short form of the Patient Activation Measure [73].
- 3) **Perceived information utility.** The utility of the intervention components will be assessed with a measure adapted from information acceptability items [75]. Additional questions are asked to assess usage of electronic media.

Process Evaluation Variables

- 1) **Intervention Use and Satisfaction.** These variables include items constructed within our ongoing projects (CISRC Projects 1 – 3) and informed by previous intervention trials [39, 42] and the recommendations of the Science Panel on Interactive Communication and Health [76] to assess use of and usability, accessibility, and satisfaction with the intervention. This measure will only be completed by participants in the intervention group.

6.6. Data Management

The Population Studies Facility (PSF) programmers will develop all software needed to execute this study. To facilitate follow-up assessment contact with each participant, PSF programmers will

develop a tickler system that reminds research staff when participants are due to receive calls. FCCC PSF programmers will also design, develop and maintain a relational database management system (RDMS) to meet the needs of this project. In the proposed study, all potential participants will be assigned a unique study identification number. Data collected will be entered onto hard-copy data collection instruments and sent to PSF for entry into the database. Detailed procedures will be employed to assure data quality.

7.0 STATISTICAL ANALYSIS

7.1. Phase 1: Focus Group Data Analysis

The nine focus groups will be audio-taped and transcribed. Information gathered from each focus group will be used to inform subsequent groups. Following completion of the ninth focus group, content analysis of the participant responses will be performed. Specifically, analyses will be guided by the C-SHIP model and our previous work with prostate cancer patients. A coding guide will be developed by identifying narrative themes related to these conceptual categories and existing empirical findings within each focus group transcript, as well as stable thematic patterns across all focus group transcripts. The research teams will code each focus group locally and a coding guide will be developed to process all qualitative analyses, which will be used at all sites. Themes and categories will be checked and rechecked by 2 research staff and one study investigator against each other to identify idiosyncratic patterns of individual transcripts and stable patterns across the study sample.

Intercoder agreement will be assessed by having each coder independently review 10 of the same samples of text. Results of their coding will be compared for consistency using a Kappa coefficient. If a Kappa of less than .75 is calculated, inconsistencies will be reviewed by the coders and PI. This will include a review of the codebook to determine if inconsistencies are the result of a coding error or if they are due to difficulties with code definitions. Difficulties will be discussed by the PI and a study investigator. Once problems are addressed and the codebook is clarified, previously coded text will be re-reviewed if necessary and intercoder agreement will be checked again. This iterative process will continue until all text has been satisfactorily coded and a final coding guide has been developed.

The final coding guide will be used to code all of the focus group transcripts into the designated categories for content analysis. Frequency of specific responses within each of these categories will be calculated, analyzed and reviewed by research staff to generate summary descriptions of the patterns obtained. Concerns and resources that are cited most frequently will be identified. The order in which individuals bring up and discuss specific needs and gaps in services and resources, and identify which themes occur in discourse closest to each other will also be noted as this can imply co-variation and association.

7.2. Phase 2: User/Usability Testing Data Analysis

User testing interviews (N=20) will be used to obtain feedback on program components, with information being used for revisions. Participants will provide feedback regarding the quality, understandability, and helpfulness of individual components. Information from the interviews will be used to guide refinement of the program prototype. Measures will include time to complete, expressions of frustration, time spent "wandering" with mouse, navigation errors, and 'back' button clicks. All measures, feedback, and comments will be compiled and evaluated to determine whether adjustments in the in the program are needed prior to the RCT.

7.3. Phase 3: Statistical Considerations for the RCT

1) Power and sample size. The sample size should allow evaluation of efficacy for both primary and secondary outcomes and also should allow evaluation of moderator effects [77]. We expect to have 240 cases per group after attrition at the 6-month follow-up. Conservatively, we set the nominal Type-1 error rate to 1%; the false discovery rate will be set to 5% using the algorithm of Benjamini and Hochberg (1995) [78]. The autocorrelation is the correlation between two measurements made on the same subject at two time points that differ by one time unit. Table 2 shows that we have robust power to detect a modest effect size of 0.10 in all cases.

Table 2: Detectable effect size in regressions with 2-sided hypothesis tests and 1% nominal Type 1 error rates

Autocorrelation	Effect size	power
0.1	0.1	96%
0.2	0.1	93%
0.4	0.1	84%

For the power analysis for the moderator effect, we will evaluate power for testing a two-way interaction ANOVA model, with the intervention and moderator the factors.

Because there are three time points, we will have three such two way ANOVAs with each at one follow-up time. We conservatively set the nominal Type 1 error rate to 0.3%. For a binary moderator with 50% data points in each category, we will have 92% power to detect an effect size of 0.18 for the interaction effect.

2) Preliminary Analyses. Descriptive and exploratory analyses will be conducted for all baseline measures to characterize the sample and describe the inferential population. The intervention and control arms will be compared using Chi-squared tests, Mann-Whitney tests or two-sample t-tests for nominal, ordinal, or continuous baseline measures, respectively. Factors significant at the 5% level will be considered confounding and will be adjusted for in further analyses.

3) Primary and Secondary Outcome Variables. The primary statistical objective is to explore the impact of VSRC-PC on the use of adaptive coping, the primary outcome variable. Multivariable linear regression will be performed to examine the effect of VSRC-PC on this variable. Post-baseline adaptive coping score will be the response measure, and baseline score, intervention, and time of the assessment will be included as the covariates. Factors identified as confounding in the preliminary analyses will be added to the model. To account for within subject correlation of the responses, we will fit the model using Generalized Estimating Equations assuming an autoregressive working correlation matrix for each subject. The same procedure will be repeated for the secondary analysis of maladaptive coping. We will account for testing multiple hypotheses using the Benjamini-Hochberg method (1995) [79] and set the false discovery rate at 5%. If the intervention improves adaptive and maladaptive coping, we will test whether the treatment effects vary over time. The interaction term between intervention and time will be added to the main effect model. If it is significant, the final model will include the interaction term. The same analyses that will be conducted on the primary outcome variable will be conducted on the secondary outcome variables.

4) Mediator and Moderator Analyses. Should the intervention demonstrate the anticipated effects on any primary and secondary outcome, a mediational analysis will be performed. The following must hold to establish a mediational effect: 1) the intervention must be associated with the mediator; 2) the mediator must reliably predict improved coping skills; 3) the significant relationship between the intervention and the outcome should be attenuated when the mediator is added to the model. Condition 1 will have been tested for aim 1 and/or 2. Condition 2 will be evaluated using similar regression models with each mediator as the response measure. Condition 3 will be assessed by adding the concurrent mediator to the final model. Mediation will be established if the correlation between intervention and the outcome is substantially diminished after adjusting for the mediator. We will also explore if the mediator affects the intervention effect over time. If the interaction between the intervention and time is significant, both the mediator and the interaction term between the mediator and time will be added to the

multivariate linear regression model from the analysis for previous aims, as suggested by Muller (2005) [80]. If the interaction between time and the intervention is substantially diminished, we will conclude that the variable mediates the change of intervention effect over time. Separate mediational analyses will be performed for each mediator variable. To assess the moderating effect of a given variable on the relationship between the intervention and adaptive coping, the interaction between the moderator and the intervention will be evaluated. Both the variable and the interaction term will be added to the linear regression model. Continuous variables will be analyzed both as a continuous variable and a binary predictor variable, with the cutoff at the median. If the interaction term is found to be significant, this will be interpreted as an indication that the variable moderates the effect of the intervention on the outcome variable, adaptive coping. Separate moderational analyses will be performed for each moderator variable.

Table 3. Univariate analyses of demographics and outcome variables by condition.		
	Intervention	Control
	N (%) or M (SD)	N (%) or M (SD)
Age	63.8 (6.7)	63.3 (7.5)
Race/ethnicity		
Non-Hispanic White	160 (73.7)	143 (67.5)
Black	40 (18.4)	51 (24.1)
Other	17 (7.8)	18 (8.5)
PSA at diagnosis (ng/ml)	14.0 (49.0)	8.6 (10.7)
Treatment completed		
Surgery Only	130 (61.0)	131 (61.8)
Radiation Only	59 (27.7)	50 (23.6)
Other (multiple treatments)	24 (11.3)	31 (14.6)
Cancer Coping		
Baseline	2.22 (0.637)	2.22 (0.673)
1 month	2.23 (0.623)	2.18 (0.673)
3 months	2.35 (0.597)	2.15 (0.633)
6 months	2.22 (0.626)	2.17 (0.643)
Profile of Mood States		
Baseline	102.8 (14.5)	100.4 (12.8)
1 month	101.9 (14.2)	99.5 (13.4)
3 months	100.2 (12.7)	100.5 (13.4)
6 months	100.2 (14.3)	102.1 (13.7)
Medical Interactions		
Baseline	2.7 (3.3)	2.4 (3.1)
1 month	2.4 (2.7)	2.2 (2.7)
3 months	2.5 (2.7)	1.9 (2.3)
6 months	2.1 (2.2)	2.0 (2.7)
EPIC		
Urinary incontinence		
Baseline	63.4 (29.7)	62.6 (30.1)
1 month	69.2 (27.0)	67.4 (26.3)

3 months	76.4 (23.8)	74.2 (24.4)
6 months	78.6 (22.3)	76.7 (23.2)
Urinary irritative		
Baseline	78.6 (19.0)	79.5 (19.4)
1 month	83.0 (17.4)	84.8 (13.5)
3 months	84.8 (15.7)	86.7 (13.2)
6 months	87.4 (15.1)	88.8 (12.7)
Bowel		
Baseline	88.7 (15.8)	89.8 (14.4)
1 month	91.5 (12.3)	91.9 (11.1)
3 months	92.1 (13.0)	93.0 (10.9)
6 months	92.6 (13.3)	91.4 (13.1)
Sexual		
Baseline	32.1 (29.2)	31.4 (29.7)
1 month	34.0 (28.9)	33.5 (31.0)
3 months	35.6 (29.4)	34.7 (29.4)
6 months	34.2 (29.4)	36.4 (28.4)

8.0. STUDY PARAMETERS/TIMELINE

Table 4. Timeline	Months									
Specific Tasks	1-6	7-12	13-16	17-24	25-30	31-36	37-42	43-48	49-54	55-60
Aim 1										
Focus groups – approaches & design										
Literature review and content identification										
Development of text, visuals, and pilot testing										
Plan and script videos										
Iterative user and usability testing										
Continue program refinement										
Final production of VSRC										
Aim 2										
Finalize study measures										
Study recruitment										
Assess baseline, 2 weeks, 2, 6, 12 months follow-up										
RCT evaluation										
Aim 3										
Exploratory aim evaluation										
Manuscript preparation										

9.0. OFF-STUDY CRITERIA

Participants will be removed from this study if a recurrence of prostate cancer occurs.

10.0. RECORDS TO BE KEPT

All information collected for this study will be kept confidential. Participants will be told that all information will be kept in strict confidence. All data will be stored on computer files or in locked filing cabinets to which only select members of the research staff will have access.

11.0. PROTECTION OF HUMAN SUBJECTS: DATA SAFETY AND MONITORING

11.1 Oversight of Monitoring. Two FCCC committees - the Research Review Committee (RRC) and the Institutional Review Board (IRB) - monitor the protection of human subjects and the safe and secure collection and storage of data. These committees assess all proposed FCCC studies before initiation and then review protocols annually. These committees ensure the scientific, technical, and statistical soundness of the research and guarantee that methods for the ethical and safe treatment of human subjects are in place. The committees scrutinize the scientific and ethical aspects of protocols and provide for an objective and ongoing assessment of the study's scientific and ethical integrity. Similar oversight committees also operate at MSMC and Rutgers Cancer Institute of New Jersey. In addition, as this is a phase III multi-site trial per NIH designation we will convene a Data Safety and Monitoring Board (DSMB) specifically for this application.

11.2. Minimization of Assessment and Intervention Adverse Effects. All possible adverse emotional reactions will be explained to participants in the informed consent document. If upon assessment or during the intervention the participant exhibits severe psychiatric symptoms or clinically high levels of emotional distress, the case will be referred to Dr. S. M., a clinical

psychologist who will, if the need is warranted, offer an appropriate referral for mental health services. In addition, with regard to potential adverse emotional reactions to the interventions, possible adverse emotional reactions will be explained to the participant in the informed consent document. Study staff will assess for adverse emotional reactions during initial data collection and during longitudinal follow-up.

11.3. Procedures for Handling Adverse Events

The protocol will employ the following mechanisms for adverse event reporting: 1) alert the study site review committees of any and all reports of adverse events; 2) inform all members of the study team of any and all reports of adverse events. If three or more adverse events are reported, the study team will assess potential causes of the adverse events and, if events are clearly linked to study participation, discontinue the study.

11.4. Quality Assurance Procedures and Participant Confidentiality.

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed subject authorization informing the subject of the following: The protected health information (PHI) that will be collected from patient; Who will have access to that information and why; Who will use or disclose that information; The rights of a research subject to revoke their authorization for use of their PHI. In the event that a respondent revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization. To ensure confidentiality is maintained at all times, respondent data will not include name. A unique study identifier will be recorded and used with electronic data collected and all records will be secured in a locked location.

We have obtained approval from our primary site for a partial waiver of HIPAA authorization for access to the medical records of prospective participants for the randomized controlled trial phase of the study. This partial waiver has been approved based on the need to prescreen prospective participants with respect to medical eligibility requirements prior to contacting them for recruitment purposes. Such prior determination of eligibility against medical requirements is in accordance with the protocol for the randomized controlled trial phase of the study and serves to facilitate participant accrual (see section 5.5, RCT Recruitment Procedures).

12.0. PARTICIPANT INFORMED CONSENT

See separate Informed Consent Documents.

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